



DEPARTMENT OF HEALTH & HUMAN SERVICES

**Public Health Service
Food and Drug Administration**

112798n

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS

Our Reference No. 29-53858

July 20, 1999

Mr. Steven J. Rudek, President
The Alternative Baking Co., Inc.
4865 Pasadena Avenue, Suite 3
Sacramento, CA 95841

WARNING LETTER

Dear Mr. Rudek:

During an inspection of The Alternative Baking Co., Inc., 4865 Pasadena Avenue, Suite 3, Sacramento, CA, 95841, conducted on January 28 and February 3, 1999, by FDA Investigator Joan T. Briones, samples of labeling for product manufactured by your firm were collected for review. The products for which labeling was collected include the Chocolate Chip, Peanut Butter, and Lemon Poppy Seed cookie products.

Our review found that these labels cause the products to be in violation of Section 403 of the Federal Food, Drug and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations (21 CFR), Part 101 - Food Labeling.

Our review of the labels disclosed the following:

- The three cookie products are misbranded under Section 403(q)(1) of the Act in that the labels do not bear nutrition labeling as specified in 21 CFR 101.9. The labels for each product bear the statement, "For nutrition info. call: 888/488-9725" but the packages are too large to qualify for the special labeling provision in 101.9(j)(13)(i) that permits a telephone number in lieu of the full nutrition label.
- The three cookie products are misbranded under Section 403(i)(1) of the Act in that the labels do not bear a complete statement of identity as required by 21 CFR 101.3, e.g., chocolate chip cookie.

- The three cookie products are misbranded under Section 403(i)(2) of the Act in that the labels do not declare the components of the ingredients which consist of two or more ingredients as specified by 21 CFR 101.4(b)(2). The components of the "wheat flour" ingredient, the "dairy-free chocolate chip" ingredient, the "peanut butter" ingredient and the "margarine" ingredient when declared as such must include a parenthetical listing of the ingredients that comprise the wheat flour, chocolate chips, peanut butter, and margarine.
- The Peanut Butter cookie product is misbranded under Section 403(a)(1) of the Act because the label bears the statement "May contain traces of nuts due to the manufacturing process". We believe this statement is misleading in this product which lists "organic peanut butter" and "unsalted crushed peanuts" as ingredients.
- The type size for the ingredient statement and the manufacturer's name and address does not meet the minimum 1/16th inch as referenced under 21 CFR 101.2(c). For instance, when upper and lower case letters are used it is the lower case "o" or its equivalent that must meet the minimum type size.
- The type size of the net weight statements appear to be smaller than the minimum for the package size. The information contained within the Establishment Inspection Report indicates that the area of the principal display panel is 16 square inches which requires a net weight statement of not less than 1/8th inch. The net weight statement on these labels is about 1/16th inch.
- The ingredient referenced as "Florida Crystals" should not be included in the ingredient declaration and the ingredient statement must not include intervening information, e.g., "contains no lactose", "lots of love", etc.

The above violations concern certain labeling requirements and are not meant to be an all inclusive list of deficiencies on your labels. Other label violations can subject the food to legal action. It is your responsibility to assure that all of your products are labeled in compliance with all applicable statutes enforced by FDA.

Furthermore, at the conclusion of the inspection, a list of insanitary conditions were listed on Form FDA 483 (Inspectional Observations) and discussed with you. Please be aware that a food is considered adulterated within the meaning of Section 402(a)(4) of the Act if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated. It is your responsibility to ensure that all requirements of the Act and regulations promulgated thereunder are being met.

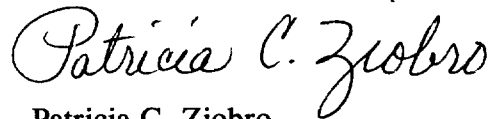
Mr. Steven J. Rudek, President, The Alternative Baking Co., Inc.

FDA Warning Letter

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Please advise us in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the noted violations along with a copy of the revised label. If corrective action cannot be completed within 15 days, state the reason for the delay and the time within which the corrections will be completed. Your response should be directed to: Ms. Davina M. Martinez, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070

Sincerely,

A handwritten signature in cursive script that reads "Patricia C. Ziobro".

Patricia C. Ziobro
Director
San Francisco District

Encl: FDA Form 483